SUBCHAPTER J—VACCINES

PART 100—VACCINE INJURY COMPENSATION

AUTHORITY: Sec. 215 of the Public Health Service Act (42 U.S.C. 216); sec. 2115 of the PHS Act; 100 Stat. 3767, as revised (42 U.S.C. 300aa–15); §100.3 Vaccine Injury Table, issued under secs. 312 and 313 of Pub. L. 99–660, 100 Stat. 3779–3782 (42 U.S.C. 300aa–1 note); and sec. 2114(c) and (e) of the PHS Act, 100 Stat. 3766 and 107 Stat. 645 (42 U.S.C. 300aa–14(c) and (e)); and sec. 904(b) of Pub. L. 105–34, 111 Stat. 873.

§100.1 Applicability.

This part applies to the National Vaccine Injury Compensation Program (VICP) under subtitle 2 of title XXI of the Public Health Service (PHS) Act.

[60 FR 7693, Feb. 8, 1995]

§100.2 Average cost of a health insurance policy.

For purposes of determining the amount of compensation under the VICP, section 2115(a)(3)(B) of the PHS Act, 42 U.S.C. 300aa.15(a)(3)(B), provides that certain individuals are entitled to receive an amount reflecting lost earnings, less certain deductions. One of the deductions is the average cost of a health insurance policy, as determined by the Secretary of Health and Human Services. The Secretary has determined that the average cost of a health insurance policy is $158.00 per month. This amount will be revised to reflect the changes in the medical care component of the Consumer Price Index (All Urban Consumers, U.S. City Average), published by the United States Bureau of Labor Statistics, plus 2 percent per year. The revised amounts will be effective upon their delivery by the Secretary to the United States Claims Court, and the amounts will be published in a notice in the FEDERAL REGISTER from time to time as determined by the Secretary.

[57 FR 28099, June 24, 1992, as amended at 60 FR 7693, Feb. 8, 1995]

§100.3 Vaccine injury table.

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Pub. L. 99–660, 100 Stat. 3779 (42 U.S.C. 300aa–1 note) and section 2114(c) of the Public Health Service Act (42 U.S.C. 300aa–14(c)), the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT).	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Brachial Neuritis	2–28 days.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.

VACCINE INJURY TABLE—Continued

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP–Hib).	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Encephalopathy (or encephalitis)	72 hours.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
III. Measles, mumps, and rubella vaccine or any of its components (e.g., MMR, MR, M, R).	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Encephalopathy (or encephalitis)	5–15 days (not less than 5 days and not more than 15 days).
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
IV. Vaccines containing rubella virus (e.g., MMR, MR, R).	A. Chronic arthritis	7–42 days.
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
V. Vaccines containing measles virus (e.g., MMR, MR, M).	A. Thrombocytopenic purpura	7–30 days.
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient.	6 months.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
VI. Vaccines containing polio live virus (OPV).	A. Paralytic Polio	
	—in a non-immunodeficient recipient ..	30 days.
	—in an immunodeficient recipient	6 months.
	—in a vaccine associated community case.	Not applicable.
	B. Vaccine-Strain Polio Viral Infection	
	—in a non-immunodeficient recipient ..	30 days.
	—in an immunodeficient recipient	6 months.
	—in a vaccine associated community case.	Not applicable.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
VII. Vaccines containing polio inactivated virus (e.g., IPV).	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Any acute complication or sequela (including death of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed..	Not applicable.
VIII. Hepatitis B. vaccines	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.

VACCINE INJURY TABLE—Continued

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
IX. Hemophilus influenzae type b polysaccharide vaccines (unconjugated, PRP vaccines).	A. Early-onset Hib disease	7 days.
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
X. Hemophilus influenzae type b polysaccharide conjugate vaccines.	No Condition Specified	Not applicable.
XI. Varicella vaccine	No Condition Specified	Not applicable.
XII. Rotavirus vaccine	No condition specified	Not applicable.
XIII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage.	No Condition Specified	Not applicable.

(b) *Qualifications and aids to interpretation.* The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table to paragraph (a) of this section:

(1) *Anaphylaxis and anaphylactic shock.* For purposes of paragraph (a) of this section, Anaphylaxis and anaphylactic shock mean an acute, severe, and potentially lethal systemic allergic reaction. Most cases resolve without sequelae. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. Autopsy findings may include acute emphysema which results from lower respiratory tract obstruction, edema of the hypopharynx, epiglottis, larynx, or trchea and minimal findings of eosinophilia in the liver, spleen and lungs. When death occurs within minutes of exposure and without signs of respiratory distress, there may not be significant pathologic findings.

(2) *Encephalopathy.* For purposes of paragraph (a) of this section, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

(A) *For children less than 18 months of age* who present without an associated seizure event, an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

(B) *For adults and children 18 months of age or older,* an acute encephalopathy is one that persists for at least 24 hours and characterized by at least two of the following:

(1) A significant change in mental status that is not medication related; specifically a confusional state, or a delirium, or a psychosis;

(*2*) A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and

(*3*) A seizure associated with loss of consciousness.

(C) Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group.

(D) A ''significantly decreased level of consciousness'' is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (b)(2)(i)(A) and (b)(2)(i)(B) of this section for applicable timeframes):

(*1*) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(*2*) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(*3*) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

(ii) *Chronic Encephalopathy* occurs when a change in mental or neurologic status, first manifested during the applicable time period, persists for a period of at least 6 months from the date of vaccination. Individuals who return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy. If a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table.

(iii) An encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known). If at the time a decision is made on a petition filed under section 2111(b) of the Act for a vaccine-related injury or death, it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the Table.

(iv) In determining whether or not an encephalopathy is a condition set forth in the Table, the Court shall consider the entire medical record.

(3) *Residual Seizure Disorder.* (i) A petitioner may be considered to have suffered a residual seizure disorder for purposes of paragraph (a) of this section, if the first seizure or convulsion occurred 5–15 days (not less than 5 days and not more than 15 days) after administration of the vaccine and 2 or more additional distinct seizure or convulsion episodes occurred within 1 year after the administration of the vaccine which were unaccompanied by fever (defined as a rectal temperature equal to or greater than 101.0 degrees Fahrenheit or an oral temperature equal to or greater than 100.0 degrees Fahrenheit). A distinct seizure or convulsion episode is ordinarily defined as including all seizure or convulsive activity occurring within a 24-hour period, unless competent and qualified expert neurological testimony is presented to the contrary in a particular case.

(ii) For purposes of paragraph (a) of this section, a petitioner shall not be considered to have suffered a residual seizure disorder, if the petitioner suffered a seizure or convulsion unaccompanied by fever (defined as a rectal temperature equal to or greater than 101.0 degrees Fahrenheit or an oral temperature equal to or greater than 100.0 degrees Fahrenheit) before the fifth day after the administration of the vaccine involved.

(4) *Seizure and convulsion.* For purposes of paragraphs (b) (2) and (3) of this section, the terms, ''seizure'' and ''convulsion'' include myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures. Absence (petit mal) seizures shall not

be considered to be a condition set forth in the Table. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

(5) *Sequela.* The term ''sequela'' means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.

(6) *Chronic Arthritis.* (i) For purposes of paragraph (a) of this section, chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

(A) Medical documentation, recorded within 30 days after the onset, of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination;

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination; and

(C) Medical documentation of an antibody response to the rubella virus.

(ii) For purposes of paragraph (a) of this section, the following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/determatomyositis, fibromyalgia, necrotizing vascultitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction) metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's syndrome, or blood disorders.

(iii) Arthralgia (joint pain) or stiffness without joint swelling shall not be viewed as chronic arthritis for purposes of paragraph (a) of this section.

(7) *Brachial neuritis.* (i) This term is defined as dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords) without involvement of other peripheral (e.g., nerve roots or a single peripheral nerve) or central (e.g., spinal cord) nervous system structures. A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is followed in days or weeks by weakness and atrophy in upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. The neuritis, or plexopathy, may be present on the same side as or the opposite side of the injection; it is sometimes bilateral, affecting both upper extremities.

(ii) Weakness is required before the diagnosis can be made. Motor, sensory, and reflex findings on physical examination and the results of nerve conduction and electromyographic studies must be consistent in confirming that dysfunction is attributable to the brachial plexus. The condition should thereby be distinguishable from conditions that may give rise to dysfunction of nerve roots (i.e., radiculopathies) and peripheral nerves (i.e., including multiple monoeuropathies), as well as other peripheral and central nervous system structures (e.g., cranial neuropathies and myelopathies).

(8) *Thrombocytopenic purpura.* This term is defined by a serum platelet count less than 50,000/mm^3. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with other causes such as hypersplenism, autoimmune disorders (including alloantibodies from previous transfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uremic syndrome. This does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura (ITP) that are mediated, for example, by viral or fungal infections, toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, rhinovirus, human immunodeficiency virus (HIV), adenovirus, and

dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. Bone marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise normal marrow.

(9) *Vaccine-strain measles viral infection.* This term is defined as a disease caused by the vaccine-strain that should be determined by vaccine-specific monoclonal antibody or polymerase chain reaction tests.

(10) *Vaccine-strain polio viral infection.* This term is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation of poliovirus from the stool is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.

(11) *Early-onset Hib disease.* This term is defined as invasive bacterial illness associated with the presence of Hib organism on culture of normally sterile body fluids or tissue, or clinical findings consistent with the diagnosis of epiglottitis. Hib pneumonia qualifies as invasive Hib disease when radiographic findings consistent with the diagnosis of pneumonitis are accompanied by a blood culture positive for the Hib organism. Otitis media, in the absence of the above findings, does not qualify as invasive bacterial disease. A child is considered to have suffered this injury only if the vaccine was the first Hib immunization received by the child.

(c) *Coverage provisions.* (1) Except as provided in paragraph (c)(2), (3) or (4) of this section, the revised Table of Injuries set forth in paragraph (a) of this section and the Qualifications and Aids to Interpretation set forth in paragraph (b) of this section apply to petitions for compensation under the Program filed with the United States Court of Federal Claims on or after March 24, 1997. Petitions for compensation filed before such date shall be governed by section 2114(a) and (b) of the Public Health Service Act as in effect on January 1, 1995, or by § 100.3 as in effect on March 10, 1995 (see 60 FR 7678, *et seq.*, February 8, 1995), as applicable.

(2) Hepatitis B, Hib, and varicella vaccines (Items VIII, IX, X, and XI of the Table) are included in the Table as of August 6, 1997.

(3) Rotavirus vaccines (Item XII of the Table) are included in the Table as of October 22, 1998.

(4) Other new vaccines (Item XIII of the Table) will be included in the Table as of the effective date of a tax enacted to provide funds for compensation paid with respect to such vaccines. An amendment to this section will be published in the FEDERAL REGISTER to announce the effective date of such a tax.

[60 FR 7694, Feb. 8, 1995, as amended at 62 FR 7688, Feb. 20, 1997; 62 FR 10626, Mar. 7, 1997; 63 FR 25778, May 11, 1998; 64 FR 40518, July 27, 1999]

PART 110 [RESERVED]